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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,554	01/18/2001	Patrick M. Alliel	200936USPCT	1650

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,554	ALLIEL ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-43 and 46-60* is/are pending in the application.

4a) Of the above claim(s) *40 and 46-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-43 and 57-60* is/are rejected.

7)☒ Claim(s) *41,57 and 58* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 March 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 22, 2003 has been entered. Claims 40-43 and 46-60 are pending. Claims 40 and 46-56 are withdrawn from consideration being drawn to non-elected methods. Should the product claims be found allowable later in prosecution, the method claims will be rejoined. Claims 41-43 and 57-60 are examined on the merits with regard to SEQ ID Nos: 1 and 3.

Response to Amendment

2. The objection to claim 41 is withdrawn in view of Applicant's amendment. The rejection of claims 38 and 41-43 under 35 U.S.C. 112, second paragraph, is either moot or withdrawn in view of Applicant's amendment.

Claim Objections

3. Claims 41, 57 and 58 are objected to for reciting non-elected sequences: SEQ ID Nos: 2, 4-8, 10, 13, 16, 17, 20, 21 and 22.

Claim Rejections - 35 USC § 112

4. Claims 41-43 and 57-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 41 is drawn to a diagnostic for "the differential detection of a HERV". There should be some basis for using the word "differential", otherwise it is not clear why it is a differential detection. Does Applicant mean that the diagnostic only detects HERV-7q, or that it detects HERV as opposed to other retroviruses? Clarification is required.
- Claim 57, section d), is unclear with regard to the meaning of "derived from". The contents of the fragment derived from an original sequence are not defined because it is not clear what is retained from the original sequence. Therefore, it is unclear what the fragment is, and a complement to such a fragment (section e) of claim 57) is also undefined. If Applicant intends that the fragment retain 14 consecutive nucleotides from the coding frame of the original sequence, then it is suggested that the language "derived from" be removed.
- Claims 60 and 61, "from amino acid 291 from the first methionine" and "from amino acid 321 from the first methionine" are unclear. Applicant defines enverin to be nucleotides 6965-9559 of SEQ ID NO: 3. With regard to claim 60, does the sequence start at the codon at nucleotide positions 8749-8751 and end at nucleotide 9550 of SEQ ID NO: 3? If so, it is not clear why amino acid 291 is referenced. Clarification is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 57 is rejected under 35 U.S.C. 102(a) as being anticipated by Alliel *et al.* (*C. R. Acad. Sci. Paris*, Life Sciences, Endogenous retroviruses and multiple sclerosis. II. HERV-7q, Vol. 321, pages 857-863, published October 1998, provided by Applicant and previously submitted with this application). The claims is drawn to a purified polynucleotide consisting of SEQ ID NO: 3, complements of SEQ ID NO: 3, reverse complements of the original sequence or the complement to the original, a fragment of SEQ ID NO: 13 having at least 14 nucleotides and a complementary sequence to the fragment. Alliel discloses SEQ ID NO: 3 by disclosing the identification of a full length endogenous retrovirus sequence called HERV-7q (abstract). Figure 1 (page 860) shows the nucleotide sequence of the open reading frame in the env region and of the 3' LTR. Figure 2 (page 861) shows the distribution of the gag, pol, env and 3' LTR regions in HERV-7q in a deduced amino acid sequence. Therefore, claim 57 is anticipated by the prior art.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alliel *et al.* as applied to claim 57, and further in view of Perron *et al.* (6,184,025). The claims are drawn to a diagnostic reagent for differential detection of a human endogenous retroviral sequence comprising a polynucleotide having a sequence selected from SEQ ID NO: 1 and 3. The diagnostic further comprises a label for detection. Alliel teaches SEQ ID NO: 3 by disclosing the identification of a full length endogenous retrovirus sequence called HERV-7q (abstract). Alliel is silent on the use of the polynucleotide for a diagnostic. However, Perron teaches the use of polynucleotides from endogenous retroviruses as diagnostics to detect endogenous retroviruses (col. 3, section (v)). It would have been obvious to use Alliel's polynucleotide as a diagnostic. One would have been motivated to use Alliel's polynucleotide as a diagnostic because it was well known at the time of the invention that polynucleotides are effective diagnostics, as evidenced by Perron. One would have had a reasonable expectation of success that Alliel's polynucleotide would have detected Alliel's HERV-7q because Perron's polynucleotide detects Perron's retroviruses. Therefore, the invention would have been prima facie obvious to one of ordinary skill in the art at the time of the invention.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

7. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 872-9306. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (571) 272-0896. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (571) 272-0902. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

James C. Housel 3/8/04

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

SBC

Stacy B. Chen
February 27, 2004